IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

DEBRA RUBERTI, Plaintiff, v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants.	)	CASE NO. 2:20-CV-874-WKW [WO]

MEMORANDUM OPINION AND ORDER

Before the court is Defendants' *Daubert* motion to exclude certain general opinions of Plaintiff's expert, Dr. Bruce Rosenzweig. (Doc. # 74-25 at 1–2.)[1] Plaintiff filed an opposition to this motion (Doc. # 75-2), and Defendants filed a reply (Doc. # 75-3). For the reasons discussed below, Defendants' motion is due to be GRANTED in part, DENIED in part, and DEFERRED in part.

I. STANDARD OF REVIEW

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (and its progeny). Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

[1] All citations use the pagination as designated by the CM/ECF filing system.

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Rule 702 assigns the trial court a gatekeeping role to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589; *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) ("[T]he Federal Rules of Evidence 'assign to the trial judge the task of ensuring that an expert's testimony rests both on a reliable foundation and is relevant to the task at hand.'" (quoting *Daubert*, 509 U.S. at 597)). This gatekeeping responsibility is the same when the trial court is considering the admissibility of "testimony based on 'technical' and 'other specialized' knowledge." *Kumho Tire Co.*, 526 U.S. at 141 (quoting Fed. R. Evid. 702).

Considering *Daubert*'s "gatekeeping requirement," the Eleventh Circuit requires district courts to engage in a "rigorous three-part inquiry" for assessing the admissibility of expert testimony under Rule 702:

> Trial courts must consider whether: "(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the

> methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue."

United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc) (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998)). These requirements are known as the "qualification, reliability, and helpfulness" prongs. *See id.*

"The burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion." *Id.* And the proponent must meet its burden "by a preponderance of the evidence." *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1232 (11th Cir. 2009); *see also Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999) ("The burden of laying the proper foundation for the admission of expert testimony is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence." (citing *Daubert*, 509 U.S. at 592 n.10)).

As to qualifications, "experts may be qualified in various ways," including by "scientific training," "education," and "experience." *Frazier*, 387 F.3d at 1260–61. "Whether a proposed expert's experience is sufficient to qualify the expert to offer an opinion on a particular subject depends on the nature and extent of that experience." *United States v. Cunningham*, 679 F.3d 355, 379 (6th Cir. 2012). "If

the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee's note (2000 amends.).

Courts must also be mindful that "[e]xpertise in one field does not qualify a witness to testify about others." *Lebron v. Sec'y of Fla. Dep't of Child. & Fams.*, 772 F.3d 1352, 1368 (11th Cir. 2014). "[S]o long as the expert is at least minimally qualified, gaps in his qualifications generally will not preclude admission of his testimony, as this relates more to witness credibility and thus the weight of the expert's testimony, than to its admissibility." *Henderson v. Goodyear Dunlop Tires N. Am., Ltd.*, Nos. 3:11-CV-295-WKW, 3:12-CV-510-WKW, 2013 WL 5729377, at *6 (M.D. Ala. Oct. 22, 2013) (alteration in original) (citation omitted).

As to reliability, trial courts retain "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho Tire Co.*, 526 U.S. at 152. The focus of reliability "must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. After all, "*Daubert* does not require certainty; it requires only reliability." *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1198 n.10 (11th Cir. 2010).

Finally, whether the expert testimony will help "'the trier of fact to understand the evidence or to determine a fact in issue'. . . goes primarily to relevance." *Daubert*, 509 U.S. at 591 (quoting Fed. R. Evid. 702). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Id.* (citation omitted). Moreover, "[o]nce an expert opinion has satisfied *Daubert*, a court may not exclude the opinion simply because it believes that the opinion is not—in its view—particularly strong or persuasive." *Seamon v. Remington Arms Co.*, 813 F.3d 983, 990 (11th Cir. 2016). Where the basis of expert testimony satisfies Rule 702, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

II. DISCUSSION

The relevant facts have been set out in a prior opinion of this court. (Doc. # 109 at 2–3.) On August 19, 2022, Defendants informed the court that there were pending *Daubert* motions that had not been resolved by the multidistrict litigation (MDL) court—U.S. District Court for the Southern District of West Virginia. (Doc. # 118.)[2] Among those pending motions was Defendants' motion to exclude certain

[2] The parties also informed the court that there remained two "recurring" *Daubert* issues that the MDL court had reserved for the trial court. (Docs. # 107 at 22–23, 118 at 2.) The first issue is expert opinions about Defendants' "compliance with design control and risk management standards." (Docs. # 71-7 at 11–12, 72-24 at 13–14, 74-20 at 14–15.) Neither party has briefed this issue or indicated where Doctors Elliott, Iakovlev, or Rosenzweig addressed this issue in their respective expert reports. And answering this question also depends, as the MDL court noted, on

general opinions of Bruce Rosenzweig, M.D. (Doc. # 74-25 at 1–2.) Dr. Rosenzweig is a licensed physician in the state of Illinois, a specialist in obstetrics and gynecology, a professor of obstetrics and gynecology, a pelvic surgeon, and a peer-reviewed author and frequent lecturer on obstetrics, gynecology, urogynecology, and urinary incontinence. (Docs. # 74-25 at 7–25, 128–29.) He has "performed over a thousand pelvic floor surgical procedures." (Doc. # 74-25 at 129.) He has "used numerous synthetic pelvic mesh products, including Ethicon's . . . TVT-Obturator [TVT-O]." (Doc. # 74-25 at 129.) And he has "performed over 300 surgeries dealing with complications related to synthetic mesh, including the removal of numerous TVT devices." (Doc. # 74-25 at 129.) He "was also invited by Ethicon and attended both its Gynecare Prolift Training Seminar and TVT Obturator Seminar in Belgium." (Doc. # 74-25 at 129.)

Defendants raise seven arguments against Dr. Rosenzweig's testimony. (Docs. # 107 at 19–22, 75-1, 74-22, 75-3, 74-24.) The court will analyze each

"state law." (Docs. # 71-7 at 12, 72-24 at 14, 74-20 at 15.) Neither party has suggested how the relevant Alabama law applies to this recurring issue. So, at this stage, the court has nothing to decide. The parties may raise this first recurring issue at trial if appropriate. The second issue is "testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments." (Docs. # 71-7 at 12, 72-24 at 14, 74-20 at 15.) Again, the parties have not briefed this issue or indicated where Doctors Elliott, Iakovlev, or Rosenzweig addressed this issue in their expert reports. Moreover, the MDL court said that it reserved "ruling on such matters until they may be evaluated in proper context . . . at trial." (Docs. # 71-7 at 13, 72-24 at 14, 74-20 at 15–16.) The court concurs. The parties may raise this second recurring issue at trial if appropriate. As to both issues, the parties are encouraged to confer and reach an agreement, with the understanding that new *Daubert* objections raised during trial will be viewed with skepticism.

argument and determine, based upon Rule 702 and *Daubert* principles, whether the objected to portions of Dr. Rosenzweig's testimony ought to be excluded.[3]

Argument # 1: Dr. Rosenzweig's opinions that alternative procedures are safer than the TVT-O are irrelevant.

In his expert report, Dr. Rosenzweig states "that the benefits of the TVT-O are outweighed by the severe, debilitating and life changing complications associated with the medical device." (Doc. # 74-25 at 235.) Dr. Rosenzweig opines that this is "especially true given that traditional surgeries like the Burch [procedure] and pubovaginal slings are not associated with the frequency or extent of [the] life changing complications" caused by the TVT-O. (Doc. # 74-25 at 235.) Dr. Rosenzweig goes on to say that "the Burch procedure," "autologous fascia slings," or "an allograft sling" "were reasonably feasible safer alternatives available to Ethicon for the treatment of patients." (Doc. # 74-25 at 236.)

Defendants argue that "the Court should preclude Dr. Rosenzweig from suggesting that [his] preferred alternatives are safer" than the TVT-O since the "comparative benefits of the traditional approaches to treat SUI [stress urinary incontinence] recommended by Dr. Rosenzweig are not even relevant to Plaintiff['s] design defect claim[], because these approaches are not even a medical device and

[3] As emphasized at the status conference held on November 1, 2022 (Doc. # 169), where other courts have already examined objections to Dr. Rosenzweig's testimony that are similar to Defendants', such prior examination will be viewed as persuasive.

do not entail altering the design of the" TVT-O. (Doc. # 75-1 at 3, 6; *see* Doc. # 107 at 19.)

It is unclear if Dr. Rosenzweig's testimony is relevant to Plaintiff's design defect claim. In three of the cases Defendants cite (Doc. # 75-1 at 4–5), the courts were applying the tort laws of different states. *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 941–42 (S.D.W. Va. 2017) ("I directed the parties to submit simultaneous briefing regarding the contours of what an alternative, feasible design can be under West Virginia law."); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-CV-978-PMP, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (applying Nevada law); *Linsley v. C.R. Bard, Inc.*, No. CIV.A.98-2007, 2000 WL 343358, at *2–3 (E.D. La. Mar. 30, 2000) (applying Louisiana law).

Defendants have not explained how the Alabama law on design defect would apply to determine the relevance of Dr. Rosenzweig's testimony. But even if Dr. Rosenzweig's testimony is ultimately irrelevant under Alabama law for Plaintiff's design defect claim, it could be relevant in another way. Fed. R. Evid. 401(a). For example, the Middle District of Florida addressed Defendants' argument "that Dr. Rosenzweig's opinions regarding safer alternatives to the TVT-O are irrelevant because he opines on safer alternative procedures rather than safer alternative designs." *Ellerbee v. Ethicon, Inc.*, No. 8:20-CV-1514-TPB, 2021 WL 2010640, at *2 (M.D. Fla. May 20, 2021). The court rejected this argument and instead found

that "Dr. Rosenzweig's opinions that alternate medical procedures were safe and effective are relevant to demonstrat[e] the product's inherent risks and [to] assist the jury in appreciating the risk-utility analysis." *Id.*

The MDL court previously addressed an identical argument from Defendants: "Ethicon argues that Dr. Rosenzweig should not be permitted to testify that alternative procedures are safer than Ethicon's mesh products" because such testimony is irrelevant. (Doc. # 74-20 at 6.) The MDL court found that "[t]he relevance of this expert testimony is better decided on a case-by-case basis" and so the court reserved "ruling until trial." (Doc. # 74-20 at 6.) Defendants have not provided a sufficient reason to depart from the MDL court's prior ruling. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) (noting that under the "law-of-the-case doctrine" "courts should be loath to" "revisit [the] prior decisions of . . . a coordinate court" unless that "decision was 'clearly erroneous and would work a manifest injustice'" (quoting *Arizona v. California*, 460 U.S. 605, 618, n.8 (1983))), *decision supplemented*, 466 U.S. 144 (1984));[4] *Cutter v. Ethicon, Inc.*, No. CV 5:19-443-DCR, 2020 WL 2060342, at *2 (E.D. Ky. Apr. 29, 2020) (finding

[4] The Middle District of Florida has noted that in the Eleventh Circuit "[t]he law of the case doctrine requires that a court not revisit the determination of an earlier equivalent court unless: (1) the evidence at a subsequent trial is substantially different; (2) controlling authority has changed; or (3) the earlier decision was clearly erroneous and would create manifest injustice." *Delgado v. Bos. Sci. Corp.*, No. 620-CV-1842, 2020 WL 13356790, at *2 (M.D. Fla. Nov. 3, 2020) (quoting *Hill v. Ford Motor Co.*, 975 F. Supp. 2d 1351, 1358 (N.D. Ga. 2013)); *see also United States v. Williams*, 728 F.2d 1402, 1405–06 (11th Cir. 1984).

that "[under] the law of the case doctrine, the [c]ourt should adopt all of the MDL's opinions regarding the outstanding *Daubert* motions to the extent possible").[5] At this stage, the court will not preclude Dr. Rosenzweig from offering testimony that alternative procedures and devices were safer than the TVT-O.

Ruling on Defendants' first argument is RESERVED for trial.

Argument # 2: The court should prevent Dr. Rosenzweig from testifying about the cut of the TVT-O mesh because his opinions are unreliable.

Defendants argue that "the [c]ourt . . . should preclude Dr. Rosenzweig from suggesting that laser-cut TVT mesh is a safer alternative to mechanically-cut TVT mesh, or vice versa" because such opinions are unreliable. (Doc. # 74-22 at 4–6; *see* Docs. # 75-1 at 6, 107 at 19–20.)

First, Defendants argue that "Dr. Rosenzweig's opinions are unreliably inconsistent." (Docs. # 74-22 at 5, 75-3 at 4, 74-24 at 3–4.) Defendants state that "[i]n his TVT and TVT-O reports, Dr. Rosenzweig opines that fraying, roping, curling, and other deformities are associated with mechanically-cut mesh and posits that laser cutting was a viable solution to correct the fraying, roping, and curling issue." (Doc. # 74-22 at 4–5.) Indeed, Dr. Rosenzweig does make such statements

[5] "Although the transferor judge has the power to vacate or modify rulings made by the transferee judge, subject to comity and 'law of the case' considerations, doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings." MANUEL FOR COMPLEX LITIGATION (FOURTH) § 20.133 (2022).

in his expert reports regarding the TVT and the TVT-O. (*See* Doc. # 74-25 at 63–75 (TVT), 161–73 (TVT-O).)

But Defendants state that, in expert reports about *other* TVT products (*e.g.*, "TVT-Exact" and "TVT-Abbrevo"), "Dr. Rosenzweig criticizes laser-cut mesh . . . and suggests that mechanically-cut mesh is preferable." (Doc. # 74-22 at 5.) Therefore, "[i]f the [c]ourt permits Dr. Rosenzweig to offer opinion testimony critiquing mechanically-cut mesh, it should preclude him from referencing laser-cut mesh as a viable alternative design, and vice versa." (Doc. # 74-22 at 5.)

If Defendants believe that Dr. Rosenzweig contradicted himself in his expert reports, then such an inquiry is best left for cross-examination. As the MDL court noted, "[t]o the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment . . . as provided by the Federal Rules of Evidence." (Doc. # 74-20 at 17.) On remand from the MDL court, other district courts have addressed a similar argument from Defendants and have rejected it. For example, the District of Nevada found that "[a]ny inconsistencies in Dr. Rosenzweig's opinions about whether laser versus mechanically cut mesh are safer alternative designs to each other are matters for cross examination, not exclusion." *Heinrich v. Ethicon, Inc.*, No. 220-CV-166-APG, 2021 WL 2290996, at *3 (D. Nev. June 4, 2021); *see also McBroom v. Ethicon, Inc.*, No. CV-20-2127-PHX, 2021 WL 2709292, at *19 (D. Ariz. July 1, 2021) (quoting *Heinrich*, 2021

WL 2290996, at *3). Because Defendants may address any alleged inconsistencies in Dr. Rosenzweig's testimony on cross-examination, such alleged inconsistencies do not justify excluding Dr. Rosenzweig's opinions.

Second, Defendants argue that "Dr. Rosenzweig's opinions lack a reliable, scientific foundation" because he "cites *no* studies in support of his opinions about complications attributable to mechanically-cut mesh"; "[h]e admits that he knows of no clinical data showing that mechanically-cut TVT mesh is associated with a statistically . . . higher rate of pain or dyspareunia than laser-cut TVT mesh"; and he allegedly stated "that 'the only study that directly compared'" the two types of mesh found a greater "*rate of erosion in the laser[-]cut mesh*." (Doc. # 74-22 at 5 (emphasis in original) (citation omitted).) In addition, Defendants argue that "from a clinical standpoint, Dr. Rosenzweig has no knowledge of ever implanting a patient with laser[-]cut mesh," so "he lacks the ability to opine based on 'experience' that there is a difference in outcome" between laser-cut and mechanically-cut mesh. (Doc. # 74-22 at 6.) "Because he cannot rely on personal experience and his opinions are not based on studies, Dr. Rosenzweig's opinions simply do not pass muster under the *Daubert* standard for expert testimony." (Doc. # 74-24 at 4.)

Other courts have heard Defendants' arguments. The District of South Dakota rejected Defendants' argument that "Dr. Rosenzweig's testimony about mechanical-cut mesh is unreliable because it is not based on any studies." *Foster v. Ethicon,*

Inc., No. 4:20-CV-4076-RAL, 2021 WL 4476642, at *11 (D.S.D. Sept. 30, 2021). The court found "that 'Dr. Rosenzweig's clinical experience with both laser-cut and mechanical-cut mesh is sufficient to satisfy the threshold reliability requirements of Rule 702.'" *Id.* (quoting *Tucker v. Ethicon, Inc.*, No. 4:20-CV-1543-RLW, 2021 WL 3910768, at *11 (E.D. Mo. Sept. 1, 2021)). The court also noted that "Dr. Rosenzweig has performed over 300 mesh-removal surgeries, 'a significant percentage' of which involved laser-cut mesh." *Id.* (citation omitted).

The District of New Hampshire also rejected Defendants' argument "that Dr. Rosenzweig failed to cite any studies in support of his opinion, rendering it unreliable." *Laderbush v. Ethicon*, *Inc.*, No. 20-CV-62-JD, 2020 WL 3001958, at *2 (D.N.H. June 4, 2020). The court noted that "Dr. Rosenzweig's opinion . . . is based on his own experience," that "[c]itation of studies in support of an opinion is a factor in determining reliability, but it is not a dispositive requirement, and [that] Ethicon does not offer any developed argument challenging whether Dr. Rosenzweig's experience is sufficient." *Id.*

The District of Arizona rejected Defendants' argument "that, from a clinical perspective, Dr. Rosenzweig's opinions on laser-cut mesh are unreliable because he does not recall ever implanting laser-cut mesh." *McBroom*, 2021 WL 2709292, at *20. The court observed that Dr. Rosenzweig possessed extensive clinical experience; he "performed more than 300 removal surgeries . . . and a significant

percentage of those involved laser-cut mesh." *Id.* The court found that "[t]his clinical experience is sufficient to satisfy the threshold reliability requirements of Rule 702." *Id.* While the court finds the analysis of these other courts persuasive, it will ultimately follow the lead of the MDL court.

The MDL court previously considered Defendants' challenge "to the reliability of Dr. Rosenzweig's expert testimony about mechanical-cut and laser-cut mesh." (Doc. # 74-20 at 6.) At that time, "plaintiffs retort[ed] that Dr. Rosenzweig's clinical experience provides a reliable foundation for this expert testimony." (Doc. # 74-20 at 6.) The court noted that "[i]n the abstract, experience—on its own or accompanied by little else—is a reliable basis for expert testimony." (Doc. # 74-20 at 6 (citing *Kumho Tire Co.*, 526 U.S. at 156).) But the court also noted that "the reliability inquiry must probe into the relationship between the experience and the expert testimony." (Doc. # 74-20 at 6–7 (quoting Fed. R. Evid. 702 advisory committee's note (2000 amends.).) The court found that it did "not have enough information to judge the reliability . . . of Dr. Rosenzweig's particular experience." (Doc. # 74-20 at 7.) In particular, the court found that it was "without sufficient information . . . to draw the fine line between reliable and unreliable expert testimony on whether mechanical-cut mesh is safer than laser-cut mesh based primarily on an expert's clinical experiences." (Doc. # 74-20 at 7.) Therefore, the court reserved "ruling until further testimony may be offered and evaluated firsthand at trial." (Doc.

74-20 at 7.) Defendants have not provided a persuasive reason to depart from the MDL court's holding. *Christianson*, 486 U.S. at 817; *Delgado*, 2020 WL 13356790, at *2. The court will reserve ruling on this matter until trial.

Therefore, for these reasons, Defendants' *Daubert* motion as to their second argument is DENIED in part and RESERVED in part.

Argument # 3: Dr. Rosenzweig is not qualified to testify about what funding and level of training Defendants should have provided physicians.

In his TVT-O expert report, Dr. Rosenzweig states that Defendants "severely cut spending on professional education and training" regarding the TVT-O. (Doc. # 74-25 at 205–06.) Defendants argue that "Dr. Rosenzweig is not qualified to testify about what funding and level of training . . . a medical device manufacturer should provide." (Doc. # 75-1 at 9; *see* Doc. # 107 at 20.) Defendants assert "his opinions are based on a narrative summary of documents rather than any special expertise." (Doc. # 75-1 at 9.) And Defendants argue that "Dr. Rosenzweig's opinions are irrelevant and prejudicial insofar as he does not claim that . . . Plaintiff's implanting physician was not appropriately trained or competent." (Doc. # 75-1 at 9.)

Several courts have agreed with Defendants. Twice, the MDL court found that Dr. Rosenzweig's opinion that Defendants provided inadequate training based off a decrease in funding "is unreliable because Dr. Rosenzweig fails to describe the basis for his opinion that Ethicon's training was inadequate." *Huskey v. Ethicon,*

Inc., 29 F. Supp. 3d 691, 706 (S.D.W. Va. 2014); *Edwards v. Ethicon, Inc.*, No. 2:12-CV-9972, 2014 WL 3361923, at *10 (S.D.W. Va. July 8, 2014). And the court found that "this opinion is simply a narrative review of corporate documents, which is not helpful to the jury." *Huskey*, 29 F. Supp. 3d at 706; *Edwards*, 2014 WL 3361923, at *10. Therefore, the MDL court excluded his opinion. *Huskey*, 29 F. Supp. 3d at 706; *Edwards*, 2014 WL 3361923, at *10.

The Middle District of Florida analyzed Defendants' argument that "Dr. Rosenzweig's criticism of the level of funding provided to train physicians by Ethicon . . . is irrelevant because no one contends that [the doctor at issue] was not properly trained." *Geery v. Ethicon, Inc.*, No. 6:20-CV-1975-RBD, 2021 WL 2580144, at *4 (M.D. Fla. Apr. 9, 2021). Based on a lack of showing "that Ethicon's training is relevant to this case, the [c]ourt preclude[d] Dr. Rosenzweig's opinion on physician training." *Id.* Similarly, the Southern District of Texas excluded "any testimony" from Dr. Rosenzweig "concerning the level of training the Defendants provided to physicians" because, in part, "no complaints have been made that . . . the treating physician . . . was improperly trained or that his care fell below the standard of care in any aspect." *Pizzitola v. Ethicon, Inc.*, No. 4:20-CV-2256, 2022 WL 6225661, at *6 (S.D. Tex. Oct. 7, 2022).

But not all courts have agreed with Defendants. The Northern District of Ohio considered Defendants' argument that Dr. Rosenzweig "should be precluded from

opining on . . . the level of training that Defendants provided to physicians concerning the use of [the] TVT-O (and the level of funding for such training)." *Olszeski v. Ethicon Women's Health & Urology*, No. 5:19-CV-1787, 2022 WL 1121362, at *4 (N.D. Ohio Apr. 13, 2022). The court allowed Dr. Rosenzweig "to opine as to . . . the level of training Defendants provided to physicians regarding the use of the TVT-O and the . . . extent to which Defendants adequately trained physicians on the risks and complications of the TVT-O." *Id.* The court found that "[s]uch testimony will assist the jury in determining the ultimate issues in the case at bar." *Id.* But the court did not permit Dr. Rosenzweig "to offer his opinion about his 'review[] [of] corporate documents showing that Ethicon cut funding for professional trainings.'" *Id.* (alterations in original) (quoting *Huskey*, 29 F. Supp. 3d at 706).

Dr. Rosenzweig has attended Defendants' training seminars (Doc. # 74-25 at 129) and has extensive experience completing surgeries related to "mesh, including the removal of numerous TVT devices" (Doc. # 74-25 at 129). These experiences indicate that he likely is qualified to opine about the training that Defendants should offer physicians who are using the TVT-O. It is less clear that Dr. Rosenzweig is qualified to opine on the alleged decrease in funding for this training. But the court will wait to decide this argument until further explanation and development at trial. Ruling on Defendants' third argument is RESERVED for trial.

Argument # 4: The court should limit Dr. Rosenzweig's product warning opinions because he is unqualified to offer such opinions.

In his TVT-O expert report, Dr. Rosenzweig opines that there were several errors and omissions in the Instructions for Use (IFU) for the TVT-O, including a failure to "include all known risks." (Doc. # 74-25 at 184–204.) Defendants seek to limit "Dr. Rosenzweig to testify[ing] about whether specific risks appear on the IFU's." (Doc. # 74-22 at 8; *see* Docs. # 75-1 at 6, 107 at 20.) Defendants seek to "preclude him from testifying about 'what information should or should not be included in an IFU.'" (Doc. # 74-22 at 8 (citation omitted).)

The MDL court has stated that "[w]hile an expert who is an obstetrician and gynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582209, at *3 (S.D.W. Va. Sept. 1, 2016). The MDL court has previously found that Dr. Rosenzweig is so qualified. *Huskey*, 29 F. Supp. 3d at 704 (discussing his experience with IFUs and his experience as a urogynecologist as reasons why he is "qualified to opine about the risks of the TVT-O . . . and whether those risks were adequately expressed in the TVT-O's IFU"); *Edwards*, 2014 WL 3361923, at *8 (same). The MDL court, therefore, found "that Dr. Rosenzweig is

qualified to testify generally on the adequacy of the TVT-O's product warnings and marketing materials." *Huskey*, 29 F. Supp. 3d at 704; *Edwards*, 2014 WL 3361923, at *8.

Defendants have offered no persuasive reason why this court should deviate from the decisions of the MDL court. Dr. Rosenzweig is an exceptionally qualified expert in obstetrics, gynecology, and urogynecology who has been found to have "the additional expertise" necessary to opine about what should be included in the TVT-O's IFU. He will be allowed to testify about the alleged deficiencies and other issues with the TVT-O's IFU at trial. Defendants' *Daubert* motion as to this argument is, therefore, DENIED.

Argument # 5: The court should exclude Dr. Rosenzweig's opinions regarding adverse event reporting because he is unqualified to offer such opinions.

In his TVT-O expert report, Dr. Rosenzweig opines that "[i]n my opinion Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate[,] and misleading." (Doc. # 74-25 at 227.) Defendants seek to preclude Dr. Rosenzweig from offering "opinions about duties allegedly owed by Ethicon as a medical device manufacturer." (Doc. # 75-1 at 6; *see* Doc. # 107 at 20–21.) Specifically, Defendants argue that the court should exclude Dr. Rosenzweig's opinions about adverse event collection and reporting because "Dr. Rosenzweig's experience as a surgeon does not qualify him to render

opinions on adverse event reporting" and "[h]e has no relevant experience . . . that would permit him to offer expert testimony regarding the standard . . . for collecting and reporting adverse events." (Doc. # 75-1 at 7.) In addition, Defendants argue that Dr. Rosenzweig's testimony is not based on any "rule or regulation" but only on his "personal belief," that his "critique of Ethicon's adverse event reporting amounts to nothing more than a narrative summary of the evidence," and that the court should preclude Dr. Rosenzweig from offering any opinions about "adverse event reporting." (Doc. # 75-1 at 7–8.)

Plaintiff responds that she does "not ask[] for reconsideration of prior orders regarding adverse event reporting," but she requests that the court "not expand the scope of any rulings regarding adverse events, such that Dr. Rosenzweig would be unable to even mention adverse event reports and how such events may not have occurred had . . . Defendant[s] actually performed testing." (Doc. # 75-2 at 10.) Moreover, Plaintiff says that Dr. Rosenzweig "will rely on particular adverse event reports as evidence to support his opinions," which was allegedly allowed by the MDL court. (Doc. # 75-2 at 10.) Defendants reply that Plaintiff is attempting "to misuse Dr. Rosenzweig 'as a conduit for corporate information by testifying about the extent of Defendants' adverse event reporting.'" (Doc. # 75-3 at 4 (quoting

Walker v. Ethicon, Inc., No. 12-CV-1801, 2017 WL 2992301, at *5 (N.D. Ill. June 22, 2017)).)[6]

Based on its reasoning regarding FDA's 510(k) clearance process, which this court addressed in a prior opinion (Doc. # 185 at 1–9), the MDL court excluded Dr. Rosenzweig's opinions about Defendants' "compliance with or violation of the FDA's . . . adverse event reporting regulations." (Doc. # 74-20 at 14.) Since Plaintiff does not contest this ruling (Doc. # 75-2 at 10), the court does not address it further. But the question remains whether the court should extend the MDL court's prohibition to *all* of Dr. Rosenzweig's testimony about Defendants' adverse event collection and reporting.

The Western District of Washington considered Defendants' effort "to exclude [Dr. Rosenzweig's] opinion that 'Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate[,] and misleading.'" *White v. Ethicon, Inc.*, No. 20-CV-952-BHS, 2022 WL 538760, at *3 (W.D. Wash. Feb. 23, 2022) (second alteration in original) (citation omitted). Defendants "argue[d] that Dr. Rosenzweig [was] not qualified to provide opinions about these topics and that he ha[d] no relevant experience that

[6] The MDL court previously said the following about corporate documents testimony: "Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his . . . expert opinions . . . he . . . may not offer testimony that is solely a conduit for corporate information." (Doc. # 74-20 at 16–17.) This restriction applies to future proceedings in this case.

would permit him to offer expert testimony regarding the standard . . . for collecting and reporting adverse events." *Id.*

The court noted the plaintiff's "response does not identify Dr. Rosenzweig's qualifications that permit him to opine on the quality of a medical device manufacturer's system for collecting adverse event reports." *Id.* at *4. The court found that the plaintiff had "not met her burden [for] establishing admissibility, as there is no evidence before the [c]ourt that would allow it to reach the conclusion that Dr. Rosenzweig is qualified to testify on this narrow issue." *Id.* Therefore, the court granted Defendants' motion and precluded Dr. Rosenzweig from opining about Defendants' collection and reporting of adverse events. *Id.*

The District of Nevada also previously addressed Defendants' argument, albeit only about adverse event collection. *Heinrich*, 2021 WL 2290996, at *4. There Defendants sought "to exclude . . . [Dr. Rosenzweig's] opinion that Ethicon's collection of adverse events and complications was incomplete, inaccurate, or misleading" because, in part, he was unqualified to offer that opinion. *Id.* The court found that the plaintiff did "not identify what in [Dr. Rosenzweig's] experience or education qualifies him to opine on the quality of a medical device manufacturer's system for collecting adverse event reports." *Id.* As a result, the court prevented Dr. Rosenzweig from providing his opinion about Defendants' adverse event collection. *Id.*

The court faces a similar situation. Defendants have objected to Dr. Rosenzweig's qualifications to opine on their collection and reporting of adverse events. Plaintiff has not provided any argument as to how or why Dr. Rosenzweig is qualified to provide his opinion on this matter. Therefore, Dr. Rosenzweig will be precluded from offering his opinion that "Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate[,] and misleading." (Doc. # 74-25 at 227.)

But he will be allowed to mention adverse event reports in his discussion of Defendants' alleged failure to test and to support his opinions generally with reference to adverse event reports. The court's ruling should not be taken as prohibiting Dr. Rosenzweig from mentioning any adverse event reports at trial. If he references an IFU, Defendants "may object as appropriate at trial." *Ellerbee*, 2021 WL 2010640, at *3. For these reasons, Defendants' *Daubert* motion as to their fifth argument is GRANTED.

Argument # 6: Dr. Rosenzweig should be precluded from opining that he TVT-O causes complications that Plaintiff did not suffer.

Defendants seek to preclude Dr. Rosenzweig from testifying "that the TVT-O causes complications that no relevant [p]laintiff—in this case, Ms. Ruberti—actually suffered." (Doc. # 107 at 21; *see also* Docs. # 75-1 at 10, 74-22 at 15.) The court has already addressed Defendants' argument in its memorandum opinion and

order on Defendants' motions *in limine*. (Doc. # 184 at 21.) There the court addressed Defendants' fourteenth motion *in limine* in which Defendants sought to "preclude Plaintiff from offering evidence of mesh-related complications other than those she actually experienced." (Doc. # 158 at 3.) In its prior opinion and order, the court reserved ruling on this question for trial or for further briefing. (Doc. # 184 at 21.) The court does the same here for the same reasons. Ruling on this argument is RESERVED for trial or, if the court deems fit, for further briefing.

Argument # 7: Dr. Rosenzweig should be precluded from offering opinions not included in his TVT-O report.

In his TVT-O expert report, Dr. Rosenzweig makes the following statement at the end of the report: "I also incorporate my past reports and testimony concerning the defects in the TVT and TVT-O." (Doc. # 74-25 at 243.) Defendants object that "Dr. Rosenzweig does not identify or limit the 'past reports' that he intends to incorporate by reference" and that this "could lead to uncertainty and confusion about what opinions [Dr. Rosenzweig] intends to provide at trial." (Doc. # 75-1 at 3 (citations omitted).) Therefore, Defendants ask that "Dr. Rosenzweig . . . be precluded from offering opinions not explicitly included in the report for [the] TVT-O." (Doc. # 107 at 21; *see* Doc. # 75-1 at 3.)

Plaintiff responds that Defendants' "argument is difficult to address because it cites no rule, court order, or edict from case law that Dr. Rosenzweig supposedly

has violated." (Doc. # 75-2 at 3.) Plaintiff states that "[t]he statements incorporating prior opinions and testimony are not intended to confuse anyone" but "are simply intended to clarify that Dr. Rosenzweig continues to hold the opinions he has reiterated dozens of times, all of which Ethicon has repeatedly been made aware of, without the need for an absurdly long report reiterating all of Dr. Rosenzweig's prior reports and testimony." (Doc. # 75-2 at 4.) Defendants reply that they "simply request[] that Dr. Rosenzweig rely on one expert report rather than vaguely referencing numerous past reports and requiring [Defendants] to guess about what opinions he intends to provide at trial." (Doc. # 75-3 at 1.)

Beyond Dr. Rosenzweig's TVT-O expert report (Doc. # 74-25 at 128–243), there may well be other statements in the record—for example, in his expert report on the TVT (Doc. # 74-25 at 27–126)—that would be useful at trial. The parties have not brought any relevant precedent to the court's attention, and independent research did not uncover any. This court will allow Dr. Rosenzweig to reference other reports and testimony, which are in the record, beyond his TVT-O report to the extent that the content referenced is relevant to the TVT-O. Fed. R. Evid. 401. For example, in a different report Dr. Rosenzweig may have made some statement about polypropylene mesh or Prolene[7] that would be applicable to his testimony about the

[7] Prolene is "Ethicon's proprietary blend of polypropylene, antioxidants, and other additives used in its mesh products." *Kaiser v. Johnson & Johnson*, No. 2:17-CV-114-PPS, 2018 WL 739871, at *2 (N.D. Ind. Feb. 7, 2018).

TVT-O. Defendants will be allowed to object at trial to any such evidence that is offered. Therefore, Defendants' *Daubert* motion as to this argument is DENIED without prejudice.

III. CONCLUSION

For the reasons provided above, it is ORDERED that Defendants' *Daubert* motion (Doc. # 74-25 at 1–2) is GRANTED in part, DENIED in part, and DEFERRED in part.

DONE this 7th day of February, 2023.

/s/ W. Keith Watkins
UNITED STATES DISTRICT JUDGE